

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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|------------------------------------|---|-------------------------------------|
| NIPPON SHINYAKU CO., LTD., |) | |
| |) | |
| Plaintiff, |) | C.A. No. 21-1015 (GBW) |
| |) | |
| v. |) | [REDACTED] |
| |) | |
| SAREPTA THERAPEUTICS, INC., |) | [REDACTED] |
| |) | [REDACTED] |
| Defendant. |) | |
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| SAREPTA THERAPEUTICS, INC. and THE |) | VOLUME 1 OF 6 (Exhibits 1-8) |
| UNIVERSITY OF WESTERN AUSTRALIA, |) | |
| |) | REDACTED - PUBLIC VERSION |
| Defendant/Counter-Plaintiffs, |) | |
| |) | |
| v. |) | |
| |) | |
| NIPPON SHINYAKU CO., LTD. |) | |
| and NS PHARMA, INC. |) | |
| |) | |
| Plaintiff/Counter-Defendants. |) | |

**DECLARATION OF MEGAN E. DELLINGER IN SUPPORT OF SAREPTA
THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN AUSTRALIA'S
MOTIONS FOR SUMMARY JUDGMENT AND MOTIONS TO EXCLUDE CERTAIN
OPINIONS AND TESTIMONY OF PLAINTIFF/COUNTER-DEFENDANTS' EXPERTS**

OUTSIDE COUNSEL EYES ONLY – SUBJECT TO PROTECTIVE ORDER

I, Megan E. Dellinger, hereby declare as follows:

1. I am an attorney at the law firm of Morris, Nichols, Arsht & Tunnell LLP and counsel for Defendant/Counter-Plaintiffs Sarepta Therapeutics, Inc. (“Sarepta”) and The University of Western Australia (“UWA”) in the above-referenced matter adverse to Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”).

2. Attached as Exhibit 1 is a true and accurate copy of U.S. Patent No. 9,994,851.

3. Attached as Exhibit 2 is a true and accurate copy of U.S. Patent No. 10,227,590.

4. Attached as Exhibit 3 is a true and accurate copy of U.S. Patent No. 10,266,827.

5. Attached as Exhibit 4 is a true and accurate copy of U.S. Patent No. 10,385,092.

6. Attached as Exhibit 5 is a true and accurate copy of U.S. Patent No. 10,407,461.

7. Attached as Exhibit 6 is a true and accurate copy of U.S. Patent No. 10,487,106.

8. Attached as Exhibit 7 is a true and accurate copy of U.S. Patent No. 10,647,741.

9. Attached as Exhibit 8 is a true and accurate copy of U.S. Patent No. 10,662,217.

10. Attached as Exhibit 9 is a true and accurate copy of U.S. Patent No. 10,683,322.

11. Attached as Exhibit 10 is a true and accurate copy of U.S. Patent No. 9,708,361.

12. Attached as Exhibit 11 is a true and accurate copy of International Patent Publication No. WO 2006/000057, bearing Bates numbers SRPT-VYDS-0007982 – SRPT-VYDS-0008103.

13. Attached as Exhibit 12 is a true and accurate copy of excerpts of NS’s Noninfringement Contentions, dated July 11, 2023.

14. Attached as Exhibit 13 is a true and accurate copy of excerpts of NS’s First Supplemental Responses and Objections to Sarepta’s Sixth Set of Interrogatories (Nos. 30-35), dated August 15, 2023.

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15. Attached as Exhibit 14 is a true and accurate copy of excerpts of the prosecution history for U.S. Patent No. 9,994,851 produced by Sarepta, bearing Bates numbers SRPT-VYDS-0002984 – SRPT-VYDS-0005241.

16. Attached as Exhibit 15 is a true and accurate copy of excerpts of the prosecution history for U.S. Patent No. 10,227,590 produced by Sarepta, bearing Bates numbers SRPT-VYDS-0005242 – SRPT-VYDS-0005992.

17. Attached as Exhibit 16 is a true and accurate copy of excerpts of the prosecution history for U.S. Patent No. 10,266,827 produced by Sarepta, bearing Bates numbers SRPT-VYDS-0005993 – SRPT-VYDS-0006843.

18. Attached as Exhibit 17 is a true and accurate copy of excerpts of the prosecution history for U.S. Patent Application No. 13/741,150 produced by Sarepta, bearing Bates numbers SRPT-VYDS-0130130 – SRPT-VYDS-0150693.

19. Attached as Exhibit 18 is a true and accurate copy of excerpts of the Opening Expert Report of Steven F. Dowdy, Ph.D., dated September 7, 2023.

20. Attached as Exhibit 19 is a true and accurate copy of excerpts of the Rebuttal Expert Report of Steven F. Dowdy, Ph.D., dated October 11, 2023.

21. Attached as Exhibit 20 is a true and accurate copy of excerpts of the Opening Expert Report of Christine C. Esau, Ph.D Regarding Infringement of Certain NS Patents, dated September 1, 2023.

22. Attached as Exhibit 21 is a true and accurate copy of excerpts of the Rebuttal Expert Report of Christine C. Esau, Ph.D Regarding Non-Infringement of the UWA Patents, dated October 11, 2023.

OUTSIDE COUNSEL EYES ONLY – SUBJECT TO PROTECTIVE ORDER

23. Attached as Exhibit 22 is a true and accurate copy of excerpts of the Expert Report of Dr. Michelle L. Hastings Regarding Invalidity of the UWA Patents, dated September 8, 2023.

24. Attached as Exhibit 23 is a true and accurate copy of excerpts of the Reply Expert Report of Dr. Michelle L. Hastings Regarding the Invalidity of the UWA Patents, dated October 27, 2023.

25. Attached as Exhibit 24 is a true and accurate copy of the Expert Report of Scott E. Kamholz, Esq., dated September 8, 2023.

26. Attached as Exhibit 25 is a true and accurate copy of the Responsive Expert Report of Scott E. Kamholz, Esq., dated October 11, 2023.

27. Attached as Exhibit 26 is a true and accurate copy of the Reply Expert Report of Scott E. Kamholz, Esq., dated October 27, 2023.

28. Attached as Exhibit 27 is a true and accurate copy of excerpts of the Opening Expert Report of Nathan W. Luedtke, Ph.D Regarding Infringement of U.S. Patent No. 10,683,322, dated September 1, 2023.

29. Attached as Exhibit 28 is a true and accurate copy of excerpts of the Reply Expert Report of Nathan W. Luedtke, Ph.D Regarding Infringement of U.S. Patent No. 10,683,322, dated October 27, 2023.

30. Attached as Exhibit 29 is a true and accurate copy of excerpts of the Expert Report of Dr. Matthew J.A. Wood, dated September 8, 2023.

31. Attached as Exhibit 30 is a true and accurate copy of excerpts of the Expert Reply Report of Dr. Matthew J.A. Wood, dated October 27, 2023.

OUTSIDE COUNSEL EYES ONLY – SUBJECT TO PROTECTIVE ORDER

32. Attached as Exhibit 31 is a true and accurate copy of excerpts of the deposition transcript of Christine Esau, dated November 3, 2023.

33. Attached as Exhibit 32 is a true and accurate copy of excerpts of the deposition transcript of Michelle Hastings, Ph.D., dated November 17, 2023.

34. Attached as Exhibit 33 is a true and accurate copy of excerpts of the deposition transcript of Scott E. Kamholz, Esq., dated November 3, 2023.

35. Attached as Exhibit 34 is a true and accurate copy of excerpts of the deposition transcript of Nathan W. Luedtke, Ph.D., dated November 15, 2023.

36. Attached as Exhibit 35 is a true and accurate copy of excerpts of the deposition transcript of Dr. Matthew J.A. Wood, dated November 10, 2023.

37. Attached as Exhibit 36 is a true and accurate copy of excerpts of the deposition transcript of Sue Fletcher, dated September 27, 2023.

38. Attached as Exhibit 37 is a true and accurate copy of excerpts of the deposition transcript of Amy Mandragouras, dated July 27, 2023.

39. Attached as Exhibit 38 is a true and accurate copy of excerpts of the deposition transcript of Stephen D. Wilton, Ph.D., dated June 15, 2023.

40. Attached as Exhibit 39 is a true and accurate copy of excerpts of the deposition transcript of Gardner Gendron, dated July 11, 2023.

41. Attached as Exhibit 40 is a true and accurate copy of excerpts of the deposition transcript of Masaya Toda, dated June 28-29, 2023.

42. Attached as Exhibit 41 is a true and accurate copy of excerpts of the deposition transcript of Naoki Watanabe, Ph.D., dated June 26-27, 2023.

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43. Attached as Exhibit 42 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00036966 – NS00036967, [REDACTED]

[REDACTED].

44. Attached as Exhibit 43 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00036879 – NS00036881.

45. Attached as Exhibit 44 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00035784 – NS00035794, [REDACTED]

[REDACTED]

46. Attached as Exhibit 45 is a true and accurate copy of Takeda et al., “Exon-Skipping in Duchenne Muscular Dystrophy,” *J. Neuromuscl. Dis.* (2021) 8:S343-S358, introduced as Exhibit 1 in the August 7-8, 2023 deposition of Shin’ichi Takeda.

47. Attached as Exhibit 46 is a true and accurate copy of Clemens et al., “Safety Tolerability, and Efficacy of Viltolarsen in Boys With Duchenne Muscular Dystrophy Amenable to Exon 53 Skipping,” *JAMA Neurology* (2020):E1-E10, which is also a document produced by NS, bearing Bates numbers NS00035339 – NS00035348, [REDACTED]

[REDACTED].

48. Attached as Exhibit 47 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00102988 – NS00103060, [REDACTED]

[REDACTED].

49. Attached as Exhibit 48 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00103061 – NS00103110, [REDACTED]

[REDACTED].

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50. Attached as Exhibit 49 is a true and accurate copy of excerpts of the Expert Report and Disclosure of Mark J. Hosfield, dated September 8, 2023.

51. Attached as Exhibit 50 is a true and accurate copy of excerpts of the deposition transcript of Mark Hosfield, dated November 1, 2023.

52. Attached as Exhibit 51 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00065827 – NS00065830, [REDACTED].

53. Attached as Exhibit 52 is a true and accurate copy of an English translation of a document produced by NS, bearing Bates numbers NS00065827 – NS00065830, [REDACTED].

54. Attached as Exhibit 53 is a true and accurate copy of a document produced by NS, bearing Bates numbers NS00036893 – NS00036908, [REDACTED].

55. Attached as Exhibit 54 is a true and accurate copy of a document produced by NS, bearing Bates number NS00091311, [REDACTED].

56. Attached as Exhibit 55 is a true and accurate copy of Harding et al., “The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping,” *Molecular Therapy*, Vol. 15, No. 1, 157-166 (2007), [REDACTED].

57. Attached as Exhibit 56 is a true and accurate copy of a document produced by NS, bearing Bates number NS00036968, [REDACTED].

OUTSIDE COUNSEL EYES ONLY – SUBJECT TO PROTECTIVE ORDER

58. Attached as Exhibit 57 is a true and accurate copy of a document produced by NS, bearing Bates number NS00091312, [REDACTED]

59. Attached as Exhibit 58 is a true and accurate copy of *W.R. Grace & Co. – Conn. v. Elysium Health, Inc.*, C.A. No. 20-1098-GBW-JLH, D.I. 291 (D. Del. Aug. 10, 2023).

60. Attached as Exhibit 59 is a true and accurate copy of Plaintiff Persawvere, Inc.’s Opening Brief in Support of Its *Daubert* Motion to Exclude Expert Testimony of Gregory Gonsalves, Ph.D., dated July 21, 2023 from *Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, C.A. No. 21-400-GBW, D.I. 138.

61. Attached as Exhibit 60 is a true and accurate copy of Defendant Milwaukee Electric Tool Corporation’s Opposition Brief to Plaintiff’s Motion to Exclude Expert Testimony of Dr. Gregory Gonsalves, dated July 28, 2023 from *Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, C.A. No. 21-400-GBW, D.I. 184.

62. Attached as Exhibit 61 is a true and accurate copy of Plaintiff Persawvere, Inc.’s Reply Brief in Support of Its *Daubert* Motion to Exclude Expert Testimony of Gregory Gonsalves, Ph.D., dated August 4, 2023 from *Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, C.A. No. 21-400-GBW, D.I. 165.

63. Attached as Exhibit 62 is a true and accurate copy of *TQ Delta, LLC v. DISH Network Corp.*, C.A. No. 15-614-RGA, D.I. 395 (D. Del. Feb. 2, 2022).

64. Attached as Exhibit 63 is a true and accurate copy of Brief for the Appellant from *Medtronic, Inc. et al. v. Comm’r of Internal Revenue*, 900 F.3d 610 (8th Cir. 2018) (No. 17-1866).

OUTSIDE COUNSEL EYES ONLY – SUBJECT TO PROTECTIVE ORDER

65. Attached as Exhibit 64 is a true and accurate copy of the Reply Expert Report of Christine C. Esau, Ph.D Regarding Infringement of Certain NS Patents, dated October 27, 2023.

66. Complete copies of any excerpted documents identified above will be provided to the Court upon request.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 11th day of December, 2023 in Wilmington, DE.

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 11, 2023, upon the following in the manner indicated:

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/s/ Megan E. Dellinger

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